PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, August 21, 2001, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Dr. Howard Koh (Chairman), Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Mr. Albert Sherman, Ms. Shane Kearney Masaschi, Mr. Benjamin Rubin and Dr. Thomas Sterne; Ms. Janet Slemenda absent (one vacancy). Also in attendance was Attorney Donna Levin, General Counsel.

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Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2. In addition, Dr. Koh announced that the docket has been revised to include a staff presentation entitled, "Flu Vaccine Availability", by Dr. Alfred DeMaria, Assistant Commissioner, and Ms. Donna Lazorik, Adult Immunization Coordinator, Bureau of Communicable Disease Control.

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The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Gregory Connolly, Director, Massachusetts Tobacco Control Program; Dr. Alfred DeMaria, Assistant Commissioner, Ms. Donna Lazorik, Adult Immunization Coordinator, Bureau of Communicable Disease Control; Dr. Paul Dreyer, Director, Division of Health Care Quality; Mr. Paul Jacobsen, Deputy Commissioner, Dept. of Public Health; Ms. Joyce James, Director, and Mr. Jere Page, Senior Analyst, Determination of Need Program; and Attorney Carl Rosenfield, Deputy General Counsel, Office of the General Counsel.

RECORDS OF THE PUBLIC HEALTH COUNCIL:

Records of the Public Health Council Meetings of June 26, 2001 and July 24, 2001 were presented to the Council for approval. After consideration, upon motion made and duly seconded, it was voted (unanimously): That Records of the Meetings of June 26, 2001 and July 24, 2001 be approved.

PERSONNEL ACTIONS:

In letters dated August 2, 2001, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointments and reappointments to the medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine

of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning August 1, 2001 to August 1, 2003:

APPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Marcus Horvath, M.D.	Provisional Active Psychiatry	158364
Lisa Price, M.D.	Provisional Affiliate Psychiatry	205404

REAPPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
John Athas, M.D.	Active	49565
Ronald Pies, M.D.	Consultant	53662
Charles Pu, M.D.	Affiliate	73771
Pradeep Reddy, M.D.	Affiliate/Consultant	75118

In a letter dated August 13, 2001, Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees'qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

PHYSICIAN APPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Mariano Ezpeleta, M.D.	Consultant/Radiology	42698
James Ming Fang, M.D.	Consultant/Internal Medicine	205245
Christopher Gill, M.D.	Consultant/Internal Medicine	205283

Ernst Manigat, M.D.	Consultant/Psychiatry	157166
Sheida Sharifi, M.D.	Consultant/Pathology	155808
Charles Stout, M.D.	Consultant/Internal Medicine	206586
JuanVera, M.D.	Consultant/Hematology Oncology	42125

PHYSICIAN REAPPOINTMENTS	**STATUS/SPECIALTY**	**MEDICAL LICENSE NO.**
Frederick Doherty, M.D.	Consultant/Radiology	34487
Carol Garner, M.D.	Consultant/ Internal Medicine	54221
Kenneth Mitchell, M.D.	Consultant/Psychiatry	80748
Ronald Nasif, M.D.	Consultant/Orthopedics	46262
Janice Rothschild, M.D.	Consultant/Surgery	57559
Elizabeth Tarnell, M.D.	Consultant/Pulmonary	73363
Jane Tsao, M.D.	Active/Surgery	77235

ALLIED HEALTH PROFESSIONAL – APPOINTMENTS	**SPECIALTY**	**MEDICAL LICENSE NO.**
Charles Reilly, Ed, CJR	Allied Health Professional	3037

Carol Walsh, RNP	Allied Health Professional	106000

ALLIED HEALTH PROFESSIONAL REAPPOINTMENTS

Beth Ferguson, PA-C	Allied Health Professional	62
Becky Heaton	Allied Health Professional	334

In a memorandum dated August 10, 2001, Howard K. Koh, Commissioner, Department of Public Health, Boston, recommended approval of an appointment of Kent Kirkpatrick to Administrator V (Director, Administration & Finance) Bureau of Health Quality Management. Supporting documentation of the appointee's qualifications accompanied the recommendation. After consideration of the appointee's qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Commissioner of Public Health, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment of Kent Kirkpatrick to Administrator V (Director, Administration & Finance) Bureau of Health Quality Management, be approved.

STAFF PRESENTATIONS:

"INFORMATIONAL UPDATE – RESEARCH ON TOBACCO SPECIFIC NITROSAMINES (TSNAs) IN ORAL SNUFF AND A REQUEST TO TOBACCO MANUFACTURERS TO VOLUNTARILY SET TOLERANCE LIMITS FOR TSNAs IN ORAL SNUFF", by Dr. Gregory Connolly, Massachusetts Tobacco Control Program

Dr. Gregory Connolly, Director, Massachusetts Tobacco Control Program, said in part, "…The Massachusetts Department of Public Health today released a new study which indicates that the level of cancer causing chemicals found in smokeless tobacco manufactured in the United States is up to 40 times greater than levels in smokeless tobacco produced in some other countries. The study, commissioned with the American Health Foundation, evaluated the levels of cancer causing agents found in U.S. and Swedish smokeless tobacco brands, also referred to as oral snuff. The study found that certain U.S. brands of oral snuff had higher levels of a cancer-causing agent, called tobacco specific nitrosmines (TSNAs) when compared to a Swedish brand and a brand produced by the Swedish firm's U.S. subsidiary. The research indicated that the level of TSNAs manufactured under the Swedish tobacco company (Match) and its U.S. subsidiary (Pinkerton Tobacco) were five to forty times lower than those products manufactured in the United States. The Massachusetts Department of Public Health is challenging the smokeless tobacco manufacturers in this country to voluntarily adopt new manufacturing processes for all brands of snuff sold in the Commonwealth to reduce TSNAs to the lowest possible levels. In the absence of voluntary action, the Massachusetts Department of Public Health will examine its own authority to regulate these cancer causing agents. This study examined only one toxin. Appropriate federal agencies should regulate all known toxins in smokeless tobacco products and conduct research to determine the impact that changes in toxin levels have on consumer's health. The bottom line of this study is that if a company can take a

cancer causing agent out a product, it should. Smokeless tobacco, or oral snuff, is widely used by younger men and adolescents. Oral snuff causes a variety of oral cancer. According to published reports, snuff raises the heart rate and blood pressure, suggesting that it may contribute to heart disease. Snuff products also deliver high doses of nicotine, which can lead to addiction. In 1985, the Massachusetts Department of Public Health declared oral snuff to be a hazardous substance, requiring health warnings on snuff packages."

"The study evaluated the TSNAs levels and the manufacturing processes in a total of six brands of oral snuff. The Department obtained brands of snuff sold in Massachusetts as well as Sweden. The American Health Foundation research found that two Swedish brands, Ettan and Timber Wolf, a Swedish subsidiary, had far lower levels of TSNAs than the standard brands available in Massachusetts. Ettan's TSNAs levels were 2.89 ug/g and TimberWolf's TSNA's levels were 7.5 ug/g, compared to domestic brand Silver Creek, which had a TSNAs level of 127.9. The differences in the TSNAs levels are due to different manufacturing processes. The Swedish Match Company, which produces Ettan, has developed a new method for manufacturing oral snuff that uses selected blends of tobacco as well as a new processing method. Some U.S. snuff manufacturers have already implemented new manufacturing processes that greatly reduce the levels of TSNAs. The study also examined the effects of the product aging, unrefrigerated, over two, four and six months. The study found that certain U.S. brands had large increases in TSNAs levels. For example, Copenhagen increased 137% over the six–month time period and Skoal increased 20%. However, there were no increased levels of TSNAs in the Swedish brand or its subsidiary tested. Research suggests refrigeration would eliminate the significant increases in carcinogen levels. The Massachusetts Tobacco Control Program is a recognized leader in tobacco control. Due to its education and awareness efforts, smokeless tobacco use by youth has been cut almost in half. In four years, the rate of smokeless tobacco use by youth fell 48%, from 9.4% in 1995 to 4.9% in 1999. The Massachusetts Tobacco Control Program's mission is dedicated to addressing the severe health risks associated with tobacco use."

No Vote/Information Only

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Note – Public Health Council Member Manthala George, Jr. left at approximately 10:20 a.m. during the staff presentation on flu vaccine availability and therefore did not vote on any further docket items.

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"<u>FLU VACCINE AVAILABILITY,</u>" by Dr. Alfred DeMaria, Assistant Commissioner and Donna Lazorik, Adult Immunization Coordinator, Bureau of Communicable Disease Control

Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Prevention, said in part, "Influenza vaccine is second only to tobacco use cessation as a potential impact in reducing respiratory viruses. There are a number of different viruses that cause cold, but influenza virus is among a handful of these viruses that cause a systemic illness with fever, muscle aches, weakness, fatigue, etc….The protection against influenza virus comes from having antibodies in the blood stream and that antibody is acquired through immunization and the reason

why we have to immunize people every year against influenza is that the virus mutates very rapidly. It changes over time. Each year there is usually a subtle difference in the vaccine because of these changes over time. The other factor that is important is that the vaccine's efficacy wanes after a few months. So, if you get immunized in October, by March or April the effect has been significantly diminished. So that is why we have to immunize people every year against influenza. And that immunization depends on having influenza vaccine to do that…"

Ms. Donna Lazorik, Adult Immunization Coordinator, spoke next. She said in part, "…In Massachusetts, the Department of Public Health purchases influenza vaccine and we think it is about half of the vaccine that is administered in the state, and this really makes Massachusetts unique among other states in the country…Every year we try to increase the amount of vaccine that is purchased…In this country, an average of twenty thousand people die of influenza every year. It can result in two hundred thousand or more hospitalizations every year and in a severe season, cost as much as twelve billion dollars. So the impact from influenza is very important. One of the priorities with influenza vaccine is everybody sixty-five years of age and older because elderly people are more at risk for complications from influenza. Since 1993, which was first year that we were measuring immunization rates in this age group, we have been making progress…"

Ms. Lazorik continued, "One of the challenges of providing influenza vaccine, particularly in the last couple of years, is the increasing cost for the vaccine. Since 1994, the cost of influenza vaccine has got up more than three hundred percent. This year the cost is four dollars and forty-nine cents per dose, and this is cost for state purchase of the vaccine. But the cost for privately purchased vaccine is going up in a similar fashion. This year we ordered seven hundred and forty thousand doses of vaccine and we have been told by the manufacturer that we can expect to get the total amount that we ordered. Last year we did not receive as much vaccine as we ordered…So, the recommendations that we have this year are similar to the ones that we had last year, that it is very important to prioritize the flu vaccine. We want to make sure that the vaccine that arrives early in the season is administered to people who are at highest risk for complications from influenza. We also want to encourage people to immunize throughout the flu season…And, finally, the use of anti-virals needs to be seen as an adjunct to vaccine, not as a substitute for the vaccine, even if the vaccine is delayed.…The Centers for Disease Control and Prevention has informed the Massachusetts Department of Public Health that, like last year, this year's influenza vaccine will arrive in several partial shipments throughout the fall. CDC is encouraging vaccine manufacturers to distribute some vaccine to all health care providers early in the season so that they can begin vaccinating their highest-risk patients. While some flu vaccine will be available in mid/late September, the Department has been notified that most of the vaccine will not be available until November."

Ms. Lazorik continued, "Every year the Department distributes state-purchased vaccine to local health departments, nursing homes, hospitals and some health care providers. State-purchased vaccine represents approximately 50% of the infuenza vaccine administered in the Commonwealth; health care providers, institutions and agencies privately purchase the rest. The Department is working with local boards of health and health care providers who receive vaccine from the Commonwealth to develop plans to ensure that when vaccine becomes available it will

be given first to the people who are most at risk of becoming seriously ill, or even dying from influenza. These people include everyone 65 years of age and older and younger people with chronic medical conditions. Influenza is a common illness, affecting 10% to 20% of the U.S. population every year. While most people recover from the flu in 1 to 2 weeks, it can be life threatening for certain groups. People at risk for complications from influenza must be the first priority for receiving flu vaccine. The cooperation of health care providers and the general public will be essential to lessening the impact of influenza. We will need the cooperation of healthy people younger than 65 years of age if we are to have enough vaccine to protect the most vulnerable members of our communities. We are urging people not at high risk for complications from influenza to wait until November to seek flu vaccine for themselves. In Massachusetts, flu season does not usually begin until December and does not peak until January or February. Because of expected delays in vaccine delivery, local health officials and businesses are being asked to schedule flu vaccination clinics no earlier than November. People who are at risk for complications from influenza however, should not wait. They should call their health care provider in early October to ask about the availability of the vaccine. There are additional steps that people can take to protect themselves. Most people who are at risk for complications from influenza are also at risk for pneumococcal disease. Pneumococcal vaccine protects people against one of the most common complications of influenza. Everyone 65 years of age and older and younger people with chronic medical conditions who have not yet received pneumococcal vaccine should contact their health care provider."

No Vote/Information Only

REGULATIONS:

REQUEST FOR APPROVAL OF EMERGENCY REGULATIONS – 105 CMR 950.000: CRIMINAL OFFENDER RECORDS CHECKS:

Mr. Paul Jacobsen, Deputy Commissioner, Massachusetts Department of Public Health said, "On November 21, 2000 and subsequently on February 27, 2001, and May 29, 2001, the Public Health Council approved requests to adopt regulations on an emergency basis entitled Criminal Offender Records Checks (105 CMR 950.000). Since emergency regulations are only effective for 90 days, the regulations are due to expire on August 27, 2001. In a separate memorandum, the final regulations concerning Criminal Offender Records Checks are presented to the Public Health Council for adoption. However, the final regulations will not be effective until published with the Secretary of State's Office, which, based on the publication schedule will not occur until September 14, 2001. Consequently, even though the Public Health Council is being asked to adopt the final regulations today, it is technically necessary to adopt the regulations on an emergency basis for the interim period until the final regulations are published. The purpose to the regulations is to establish standardized procedures for the Department of Public Health and its contracted vendors with respect to the review of criminal records of candidates for employment or regular volunteer or training positions. The regulations require the Department and programs funded by the Department to request criminal offender record information (CORI) for every candidate for a position that will involve the potential for unsupervised contact with program clients, and to review that information to determine if the individual is appropriate to be

hired under the guidelines set out in the regulations. The Public Health Council is requested to adopt these regulations on an emergency basis so that they will remain in effect until the final regulations become effective on September 14, 2001."

After consideration, upon motion made and duly seconded, it was voted: unanimously (Council Member Manthala George, Jr. not present to vote) **to approve the Request for Approval of Emergency Regulations – 105 CMR 950.000: Criminal Offender Record Checks**; that a copy of the emergency regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the emergency regulations be attached and made a part of this record as **Exhibit Number 14,715**.

REQUEST FOR APPROVAL OF FINAL REGULATIONS – 105 CMR 950.000: CRIMINAL OFFENDER RECORDS CHECKS:

Mr. Paul Jacobsen, Deputy Commissioner, Massachusetts Department of Public Health, presented the Request for Final Adoption of 105 CMR 950.000: Criminal Offender Record Checks. Mr. Jacobsen began, "On November 21, 2000 and subsequently on February 27, 2001, and May 29, 2001, the Public Health Council approved requests to adopt regulations on an emergency basis entitled Criminal Offender Record Checks (105 CMR 950.000). The purpose of the regulations is to establish standardized procedures for the Department of Public Health and its contracted vendors with respect to the review of criminal records of candidates for employment or regular volunteer or training positions. The regulations require the Department and programs funded by the Department to request criminal offender record information (CORI) for every candidate who will have the potential for unsupervised contact with program clients, and to review that information to determine if the individual is appropriate to be hired under the guidelines set out in the regulations. The Department held a public hearing on January 19, 2001 for the purpose of receiving comment on the regulations. More than 60 people testified at that time, and the Department received more than 120 written comments."

Mr. Jacobsen continued, "The regulations establish four categories of criminal offenses that might show up on a CORI Check: mandatory disqualification, ten-year presumptive disqualification, five-year presumptive disqualification and discretionary disqualification.

- In the event that a candidate for employment or a volunteer or trainee position has a mandatory disqualification, that candidate will be ineligible for any position that involves potential unsupervised contact with a client of a program operated or funded by the Department.

- Candidates with a 5 or 10 year presumptive disqualification may be eligible for positions involving potential unsupervised contact with clients, but only after the 5 or 10-year period has passed or the candidate's probation officer, parole officer or other criminal justice official, or forensic psychiatrist or psychologist concludes in writing that the candidate is appropriate for the position. Further, the hiring authority must then conduct a review to determine that the candidate does not pose a danger to clients.

- An individual with a discretionary disqualification may be eligible for a position involving potential unsupervised client contact only after the employer conducts a review to determine that the candidate does not pose a danger to clients.

Prior to adoption of the emergency regulations by the Department and other EOHHS agencies, several individuals challenged the validity of the EOHHS policy on criminal background checks which predated the regulations, and served as the basic model for the regulations. The case, which was filed in Superior Court, is entitled Cronin et al. vs. O'Leary. On August 9, 2001, Superior Court Judge Ralph D. Gants reviewed the emergency regulations promulgated by the agencies and ruled on one part of the case concerning whether it was constitutionally permissible to have a mandatory lifetime disqualification from employment in EOHHS human service positions. Judge Gants ruled that this type of disqualification deprived plaintiffs of a constitutional liberty interest, and found that individuals who had been convicted of crimes on the mandatory list were entitled to an opportunity to rebut the presumption that they pose too great a danger to work with human service clients.

The Department has reviewed and seriously considered all the testimony submitted and the partial ruling in the Cronin case. Since these regulations are part of a secretariat-wide initiative, Department staff have worked with representatives from the Executive Office of Health and Human Services and other human service agency representatives to discuss possible revisions to the regulations. During these discussions, an effort was made to strike the appropriate balance between the protection of clients, reasonable restrictions on those with a criminal record to work in human services, and the hiring authority's ability to exercise discretion in hiring. The administration intends to appeal the decision in the Cronin case, and is expecting that the validity of the regulations will be upheld on appeal. Consequently, the proposed final regulations retain the mandatory category. The following are the major changes that were accepted by the Executive Office and will be included in the regulations of all human service agencies within the Secretariat:

1. Changes to the disqualifications lists:

- The crimes of armed carjacking, home invasion, inducing a minor to prostitution, malicious explosion and mayhem were added to the mandatory list. Larceny was added to the discretionary list. The Department was informed that these crimes were inadvertently left off the original list prepared by EOHHS. 950.200

- An outstanding warrant will result in a mandatory disqualification unless and until it is removed. A pending crime (defined as an offense which remains open and without final resolution, including a case continued without a finding) will result in the same disqualification as a conviction for that crime as indicated on the lists until there is a final resolution. 950.105

- Accessory before any crime in a category or attempts to commit any crime in a category result in the same disqualification as the crime itself. 950.200, 201, 202 and 203.

2. The requirement for review by a designated forensic psychiatrist or psychologist is revised to allow for review by a qualified mental health professional. This new term is broader and defined to include a psychiatrist, psychologist, or a licensed independent clinical social worker with at least 1,000 hours of experience over a minimum of two years involving the assessment, treatment, and consultation concerning individuals with behavior that presents a risk of harm to others in the community, in the workplace, in treatment settings, or in correctional facilities. EOHHS added the requirement that the qualified mental health professional must not have "provided treatment to the candidate" and can not be "an employee of the hiring authority". 950.005

3. The requirement that a candidate for employment disclose all crimes which he or she has been convicted of, and the requirement that the hiring authority compare this disclosure with the CORI results were deleted due to a conflict with a provision of the Massachusetts Commission Against Discrimination statute. The section now tracks the provisions of the statute, which prohibit an employer from asking about certain crimes. It should be noted however, that this does not preclude an employer from asking a candidate for consent to get all CORI information, including these crimes from the Criminal History Systems Board. 950.100

4. The section on community service and work release workers was revised to clarify that these workers may work at a Department or vendor agency program only if the criminal justice official concludes in writing that the individual will not pose an unacceptable risk of harm to program clients or will be supervised by the community service or work release program staff at all times. This language tracks the language in the EOHHS regulations. 950.101

5. A waiver provision was added which allows the Department to grant an exemption from the requirements relating to the 10 and 5-year presumptive categories to a vendor agency program, when the Department determines that the exemption is warranted on the basis of consideration of the following criteria:

- The service needs and level of vulnerability of the clients served by the program
- The potential benefits and risks to those clients as a result of the exemption
- The hiring authority's capacity to perform the review required under the discretionary exemption provisions of the regulations.

Programs which serve clients 16 years of age or under or a population that is primarily 65 years of age or older are not eligible for the waiver.

This waiver provision does not apply to individuals convicted of a crime in the mandatory category. 950.107

6. A provision was added requiring the hiring authority to inform the candidate who has otherwise met the requirements for further consideration of the opportunity to submit other additional information. In addition, the regulations now require written documentation of the

appropriateness for employment for each candidate awarded a position after the final discretionary review process is completed. 950.106

7. A provision was added to clarify that nothing in the regulations precludes the hiring authority from considering other criminal convictions not included in the regulations. 950.204

Other minor substantive changes and edits to clarify the meaning of certain provisions were also made. The Public Health Council is respectfully requested to adopt the revised version of the emergency regulations (Attachment VI) which reflect the changes discussed above, as final regulations. These regulations are consistent with the regulations which will be promulgated by the Executive Office of Health and Human Services and the other agencies within the Secretariat."

After consideration, upon motion made and duly seconded, it was voted: unanimously (Council Member Matt George Jr. not present to vote) **to approve the Request for Approval of Final Regulations – 105 CMR 950.000: Criminal Offender Record Checks**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the approved regulations be attached to and made a part of this record as **Exhibit Number 14,716.**

REQUEST FOR FINAL PROMULGATION OF AMENDMENT TO DETERMINATION OF NEED REGULATIONS 105 CMR 100.000 GOVERNING TRANSFER OF SITE PROCEDURES:

Dr. Paul Dreyer, Director, Division of Health Care Quality, said in part, "The purpose of this memorandum is to request the Public Health Council's approval of final promulgation of the amendment to the Determination of Need Regulations 105 CMR 100.720, Transfer of Site Procedures. This amendment does the following: a) defines the "population served by the facility" with respect to the transfer of site of a project approved pursuant to 105 CMR 100.530 and not yet licensed or in operation, or a facility duly licensed pursuant to M.G.L. sections 51-53 or M.G.L. c. 111B, sections 6, 6A or 6B; b) adds another review standard to increase access in undeserved areas; and c) allows relocation of a long-term care facility outside its service area provided access is significantly improved. The Public Health Council was briefed on the proposed amendment on October 24, 2000. A public hearing on the proposed amendment was held on May 23, 2001 in the Public Health Council Conference Room. Four people attended the hearing. One person, Edward D. Kalman, representing New England Sinai Hospital and Rehabilitation Center (NESH), testified. Written comments were received from Brockton Hospital and Mr. Kalman on behalf of NESH. Mr. Kalman stated that the proposed rule defines a facility's primary service area "…as the population residing in the cities and towns that each account for 5% or more of cumulatively 90% of the facility's service-specific and age-specific annual inpatient discharges or outpatient visits." He indicated that the definition is based on medical/surgical bed need guidelines, which were not applicable to non-acute care hospitals such as NESH and had no relationship to outpatient services. He also indicated that the primary service area definition was inappropriately applied to the rule that allows transfer to a new site and should be deleted. He argued that the facility would not have located services at the new site at the time the application was filed and therefore would not have a primary service area.

Brockton Hospital recommended that outpatient visits be deleted from the definition of primary service area."

Dr. Dreyer continued, "Staff agrees that the definition of a primary service area in the proposed regulation is based on the medical/surgical bed need methodology, which might be difficult for non-acute care hospitals to implement since the relevant data are not easily available to them. The definition of a primary service area has been revised to require only patient origin data, which are available to both acute and non-acute care hospitals. The new definition of the population served by the facility includes cities and towns that cumulatively account for 75% of the hospital's total discharges. Regulations 100.720 (H) (1) and (I)(1) are revised accordingly. Staff notes that 100.720(H)(1) and (I)(1) also include language that would prevent a transfer of site from resulting in a duplication of services. Also, in response to Mr. Kalman's comments language relating to the primary service area of a new site is deleted from 100.720(H)(2) and (I)(2). Regarding Brockton Hospital's comment, the revised primary service area makes no reference to outpatient visits. Staff recommends the Public Health Council's adoption of the amendment."

After consideration, upon motion made and duly seconded, it was voted: unanimously (Council Member Manthala George, Jr. not present to vote) **to approve the Request for Final Promulgation of Amendment to Determination of Need Regulations 105 CMR 100.000 Governing Transfer of Site Procedures**; that a copy of the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy of the amended regulations be attached to and made a part of this record as **Exhibit Number 14,717.**

DETERMINATION OF NEED PROGRAM:

CATEGORY 2 APPLICATION:

PROJECT APPLICATION NO. 5-3A01 OF NEW ENGLAND SINAI HOSPITAL AND REHABILITATION CENTER TO ADD 21 CHRONIC DISEASE BEDS IN EXISTING SPACE AT THE HOSPITAL'S MAIN CAMPUS:

Ms. Joyce James, Director, Determination of Need Program, said in part, "New England Sinai Hospital and Rehabilitation Center (NESH) filed a Determination of Need application to add 21 chronic disease beds in existing space at the main campus of New England Sinai Hospital and Rehabilitation Center. New England Sinai Hospital noted that the requested 21 beds will reestablish its licensed bed capacity to 212 beds, the number of beds for which the Hospital was licensed prior to its 1997 decision to license and operate 21 of its chronic disease beds as Skilled Nursing Facility (SNF) beds. However, due to the financial impact of changing federal reimbursements for SNFs, New England Sinai Hospital closed the SNF unit in May 2000."

After consideration, upon motion made and duly seconded, it was voted: Chairman Koh, Ms. Masaschi, Ms. Cudmore, Dr. Sterne, Mr. Rubin in favor and Mr. Sherman abstaining due to 268A; (Mr. George, Jr. not present to vote), **to approve Project Application No. 5-3A01 of New England Sinai Hospital & Rehabilitation Center** to add 21 chronic disease beds in

existing space at the hospital's main campus, (summary of which is attached to and made a part of this record as **Exhibit Number 14,718**), based on staff findings, with a maximum capital expenditure of $200,000 (June 2001 dollars) and first year incremental operating costs of $432,462 dollars. As approved, the application provides for the addition of twenty-one (21) chronic disease beds in existing space at the main campus of New England Sinai Hospital & Rehabilitation Center. This Determination of Need is subject to the following conditions:

1. New England Sinai Hospital and Rehabilitation Center shall accept the maximum capital expenditure of $200,000 (June 2001 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2. New England Sinai Hospital shall not transfer any beds (existing or new) either from the facility's main site or existing satellites to other sites for a period of twelve (12) months after adding beds to the hospital's main site under these revised guidelines; provided that a transfer of beds from an existing satellite to a new satellite may be permitted if the transfer does not result in a net increase in satellite beds, the transferred beds are operational at the time the transfer of site application is filed, and the transfer otherwise meets the provisions of 105 CMR 100.720.

ALTERNATE PROCESS FOR TRANSFER OF OWNERSHIP APPLICATION:

PROJECT APPLICATION NO. 3-3999 OF ESSENT HEALTHCARE OF MASSACHUSETTS, INC. – REQUEST FOR TRANSFER OF OWNERSHIP AND ORIGINAL LICENSURE OF HALE HOSPITAL, RESULTING FROM ACQUISITION OF HALE HOSPITAL'S REAL ESTATE AND ASSETS BY ESSENT HEALTHCARE, INC.:

Mr. Jere Page, Senior Analyst, Determination of Need, said in part, "…Essent Healthcare, Inc., through its wholly owned subsidiary, Essent Healthcare of Massachusetts, Inc., is seeking transfer of ownership and original licensure of Hale Hospital located at 140 Lincoln Avenue, Haverhill, MA. The transfer of the Hospital results from a response by Essent Healthcare, Inc. to a Request for Proposal (RFP) issued by the City of Haverhill for the purchase or lease of the Hospital's real estate and the purchase of the Hospital's assets. Essent Healthcare of Massachusetts, Inc. will be the licensee of Hale Hospital. Regarding future changes in service resulting from this transfer of ownership, Staff notes that the Hospital has temporarily suspended maternity and pediatric services. No capital expenditures are contemplated for this transfer of ownership…Based upon a review of the application as submitted and clarification of issues by the applicant, Staff finds that the application satisfies the requirements for the Alternate Process for Change of Ownership found in 105 CMR 100.600 et seq. Staff also finds that the applicant satisfies the standards applied under 100.602 as follows:

A. With adherence to a certain condition, individuals residing in Hale Hospital's primary service area will comprise a majority of the individuals responsible for decisions concerning:

1. Approval of borrowings in excess of $500,000;

2. Additions or conversions which constitute substantial changes in service;
3. Approval of capital and operating budgets; and
4. Approval of the filing of an application for determination of need.

B. The applicant has consulted with the Division of Medical Assistance (DMA) concerning the access of medical services to Medicaid recipients to the Hospital. Comments from the DMA indicate no access problems for Medicaid recipients in the Hospital's primary service area.

C. The Division of Health Care Quality has determined that the applicant and any health care facility affiliates have not been found to have engaged in a pattern or practice in violation of the provisions of M.G.L.c.11,s.51(D).

D. The applicant has agreed to maintain or increase the percentage of gross patient service revenue allocated to free care, as defined in M.G.L. c.118G or its successor statute covering uncompensated care, as existed prior to the transfer. The percentage of gross patient service revenue allocated to free care in FY 2000 at Hale Hospital was 2.46%.

E. Essent Healthcare of Massachusetts, Inc., pending acquisition of Hale Hospital, will be an affiliate of the Hospital, which is licensed by the Department."

Mayor James A. Rurak, Haverhill, Massachusetts, said in part, "The City accepts and welcomes the recommendations of the Staff and we welcome the conditions as well…I think we can move forward and preserve an acute care hospital in the City of Haverhill. We regret that we had to curtail some services…"

Mr. W. Hudson Connery, President and Chief Executive Officer, Essent Healthcare of Massachusetts, Inc., said in part, "Essent is a new company formed in 1999 for the sole purpose of the ownership of what we call essential community hospitals, and we have felt for a long time that Hale Hospital in Haverhill clearly fits our definition of an essential hospital…Not all hospitals in the country are going to survive. We are going through tough times. We are very selective about those communities that we choose to make investments in and about our resources, too. The management team of Essent has anywhere from ten to thirty years of community hospital experience woven through operations, finance and senior leadership, as well as a private investing firm. This is the fourth hospital company that they have started from scratch. Three others are all publicly traded. We have a long history about the terms of financing and operating community hospitals…I will note today that we have made great progress with two of the three principal managed care organizations…I move to a comment of optimism, that we can in fact, pull off this transaction and the Hale Hospital will continue its ninety years of service to the community. With that, I would just like to end with praise for the people of the state government, and for the people in this department, the Commissioner and others, who first met with me and provided a lot of guidance, a lot of support, a lot of understanding to this situation…So I am honored to be here today and hopefully we will receive your support."

After consideration, upon motion made and duly seconded, it was voted unanimously: to **approve the Alternate Process for Transfer of Ownership Application, Project Application No. 3-3999 of Essent Healthcare of Massachusetts, Inc. – Request for transfer of ownership and original licensure of Hale Hospital**, resulting from acquisition of Hale Hospital's real estate and assets by Essent Healthcare, Inc., a summary is attached and made a part of this record as **Exhibit Number 14,719**.

This approval is subject to the following conditions:

1. The applicant has agreed to maintain or increase, for an indefinite period, the percentage of gross patient service revenue allocated to free care, as defined in M.G.L.c118G or its successor statute covering uncompensated care, as existed prior to the transfer. The percentage of gross patient service revenue allocated to free care at Hale Hospital by Essent Healthcare of Massachusetts, Inc. shall be 2.46%.

2. The applicant will solicit from the community, including the Boards of Health of the Hospital's primary service area communities, names of qualified candidates who live or work in these communities and could serve on the Hospital's Local Board of Trustees, which will have responsibility for the decisions set forth in Standard A. At least fifty percent (50%) of the Local Board will be filled in this manner. The Board should reflect the diversity of the Hospital's service area, both geographic and with regard to culture, race, ethnicity, age, gender and disability, among other factors.

The meeting adjourned at 11:15 a.m.

LMH/sb

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Howard K. Koh, M.D., M.P.H.
Chairman